Claims

1. A bispecific binding molecule, whereby said molecule comprises or consists of at least two domains,

   (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is

      (i) an amino acid sequence of SEQ ID NO: 2;

      (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1;

      (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and

      (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii)

   with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and

   (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

2. The bispecific binding molecule according claim 1, wherein the domain which binds to/interacts with the human CD3 complex is characterized by having a serine at position L24, a valine at position L54 and a leucine at position L96.

3. The bispecific binding molecule according to claim 1 or 2, wherein the CDR region of said light chain comprises or consists of the amino acid sequence of SEQ ID NOs: 4, 6 or 8 or encoded by a nucleic acid sequence of SEQ ID NOs: 3, 5 or 7.

4. The bispecific binding molecule according to any of claims 1 to 3, wherein the domain which binds to/interacts with the human CD3 complex is a scFv.

5. The bispecific binding molecule according to any of claims 1 to 4, wherein said domain which binds to/interacts with the human CD3 complex comprises or consists of the amino acid sequence of SEQ ID NO: 10 or is encoded by a nucleic acid sequence of SEQ ID NO: 9.

6. The bispecific binding molecule according to any of claims 1 to 5, wherein the domain which binds to/interacts with the human CD3 complex comprises or consists of the amino acid sequence as depicted in SEQ ID NO.: 14 or encoded by a nucleic acid sequence of SEQ ID NO: 13.

7. The bispecific binding molecule according to any of claims 1 to 6, wherein said second domain is at least one further antigen-interaction-site specific for one or more cell surface molecule(s).

8. The bispecific binding molecule according to claim 7, wherein said one or more cell surface molecule(s) is/are a tumor specific molecule(s).

9. The bispecific binding molecule according to claim 7 or 8, wherein said second domain is a further scFv.

10. The bispecific binding molecule according to any of claims 7 to 9, wherein said second domain specifically binds to/interacts with an antigen selected from the group consisting of EpCAM, CCR5, CD19, HER-2, HER-3, HER-4, EGFR, PSMA, CEA, MUC-1 (mucin), MUC2, MUC3, MUC4, MUC5AC, MUC5B, MUC7, bhCG, Lewis-Y, CD20, CD33, CD30, ganglioside GD3, 9-O-Acetyl-GD3, GM2, Globo H, fucosyl GM1, Poly SA, GD2, Carboanhydrase IX (MN/CA IX), CD44v6, Sonic Hedgehog (Shh), Wue-1, Plasma Cell Antigen, (membrane-bound) IgE, Melanoma Chondroitin Sulfate Proteoglycan (MCSP), CCR8, TNF-alpha precursor, STEAP, mesothelin, A33 Antigen, Prostate Stem Cell Antigen (PSCA), Ly-6 desmoglein 4, E-cadherin

neoepitope, Fetal Acetylcholine Receptor, CD25, CA19-9 marker, CA-125 marker and Muellerian Inhibitory Substance (MIS) Receptor type II, sTn (sialylated Tn antigen; TAG-72), FAP (fibroblast activation antigen), endosialin, EGFRvIII, L6, SAS, CD63, TF-antigen, Cora antigen, CD7, CD22, Igα, Igβ, gp100, MT-MMPs, F19-antigen and CO-29.

11. The bispecific binding molecule according to claim 10, wherein said second domain comprises or consists of an amino acid sequence selected from the group of:
    (a) an amino acid sequence corresponding to SEQ ID NO.: 16 or 18;
    (b) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO.: 15 or 17;
    (c) an amino acid sequence encoded by a nucleic acid sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (b) under stringent hybridization conditions; and
    (d) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (b) and (c).

12. The bispecific binding molecule according to claim 11, wherein said molecule comprises or consists of an amino acid sequence selected from the group of:
    (a) an amino acid sequence corresponding to SEQ ID NO.: 20
    (b) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO.: 21;
    (c) an amino acid sequence encoded by a nucleic acid sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (b) under stringent hybridization conditions; and
    (d) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (b) and (c).

13. The bispecific binding molecule according to claim 10, wherein said second domain comprises or consists of an amino acid sequence selected from the

group of:

(a) an amino acid sequence corresponding to SEQ ID NO.: 22, 24, 26, 28, 30, 32;

(b) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO.: 21, 23, 25, 27, 29, 31;

(c) an amino acid sequence encoded by a nucleic acid sequence hybridizing with the complementary strand of a nucleic acid sequence as de-fined in (b) under stringent hybridization conditions; and

(d) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (b) and (c).

14. The bispecific binding molecule according to claim 13, wherein said molecule comprises or consists of an amino acid sequence selected from the group of:

(a) an amino acid sequence corresponding to SEQ ID NO.: 34, 36

(b) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO.: 33, 35;

(c) an amino acid sequence encoded by a nucleic acid sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (b) under stringent hybridization conditions; and

(d) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (b) and (c).

15. The bispecific binding molecule according to any of claims 7 to 11 or 13, wherein said at least one further antigen-interaction-site is humanized.

16. A nucleic acid sequence encoding a bispecific binding molecule according to any of claims 1 to 15.

17. The nucleic acid molecule of claim 16 comprising a nucleotide sequence selected from the group consisting of:

(a) a nucleotide sequence encoding the mature form of a protein comprising the amino acid sequence selected from the group of SEQ ID NOs: 20, 34, 36;

(b) a nucleotide sequence comprising or consisting of a DNA sequence selected from the group of SEQ ID NOs: 19, 33, 35;

(c) a nucleotide sequence hybridizing with the complementary strand of a nucleotide sequence as defined in (b) under stringent hybridization conditions;

(d) a nucleotide sequence encoding a protein derived from the protein encoded by a nucleotide sequence of (a) or (b) by way of substitution, deletion and/or addition of one or several amino acids of the amino acid sequence encoded by the nucleotide sequence of (a) or (b);

(e) a nucleotide sequence encoding a protein having an amino acid sequence at least 60 % identical to the amino acid sequence encoded by the nucleotide sequence of (a) or (b);

(f) a nucleotide sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (a) to (e).

18. A vector comprising a nucleic acid sequence according to claim 16 or 17.

19. The vector of claim 18, which further comprises a nucleic acid sequence which is a regulatory sequence operably linked to said nucleic acid sequence according to claim 16 or 17.

20. The vector of claim 18 or 19, wherein the vector is an expression vector.

21. A host transformed or transfected with a vector according to any of claims 18 to 20.

22. A process for the production of a bispecific binding molecule according to any of claims 1 to 15, said process comprising culturing a host of claim 21 under

conditions allowing the expression of the bispecific binding molecule and recovering the produced bispecific binding molecule from the culture.

23. A composition comprising a bispecific binding molecule according to any of claims 1 to 15 or as produced by the process of claim 22, a nucleic acid molecule of claim 16 or 17, a vector of any one of claims 18 to 20 or a host of claim 21 and, optionally, a proteinaceous compound capable of providing an activation signal for immune effector cells.

24. The composition of claim 23 which is a pharmaceutical composition further comprising suitable formulations of carrier, stabilizers and/or excipients.

25. The composition of claim 23 which is a diagnostic composition further comprising means and methods for detection of proliferative diseases, tumorous diseases, inflammatory diseases, immunological disorders, autoimmune diseases, infectious diseases, viral diseases, allergic reactions, parasitic reactions, graft-versus-host diseases or host-versus-graft diseases.

26. Use of the bispecific binding molecule according to any of claims 1 to 15 or as produced by the process of claim 22, the nucleic acid molecule of claim 16 or 17, the vector of any one of claims 18 to 20 or the host of claim 21 for the preparation of a pharmaceutical composition for the prevention, treatment or amelioration of a proliferative disease, a tumorous disease, an inflammatory disease, an immunological disorder, an autoimmune disease, an infectious disease, viral disease, allergic reactions, parasitic reactions, graft-versus-host diseases or host-versus-graft diseases.

27. A method for the prevention, treatment or amelioration of a proliferative disease, a tumorous disease, an inflammatory disease, an immunological disorder, an autoimmune disease, an infectious disease, viral disease, allergic reactions, parasitic reactions, graft-versus-host diseases or host-versus-graft diseases in a subject in the need thereof, said method comprising the step of administrating an effective amount of the bispecific

binding molecule according to any of claims 1 to 15 or as produced by the process of claim 22, the nucleic acid molecule of claim 16 or 17, the vector of any one of claims 18 to 20 or the host of claim 21.

28. The method of claim 27, wherein said subject is a human.

29. The method of claim 27 or 28 further comprising the administration of a proteinaceous compound capable of providing an activation signal for immune effector cells.

30. The method of claim 29, wherein said proteinaceous compound is administered simultaneously or non-simultaneously with the bispecific binding molecule according to any of claims 1 to 15 or as produced by the process of claim 22, the nucleic acid molecule of claim 16 or 17, the vector of any one of claims 18 to 20 or the host of claim 21.

31. A kit comprising the bispecific binding molecule according to any of claims 1 to 15 or as produced by the process of claim 22, the nucleic acid molecule of claim 16 or 17, the vector of any one of claims 18 to 20 or the host of claim 21.